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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

22865 7590 09/30/2003

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/30/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/186,810

Applicant(s)

CARLYLE ET AL.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-10,13-15,28,29 and 33-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,29 and 33 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-10,13-15,33-41,43 and 44 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 1, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 appears to limit the claim to a crosslinking agent only because the word "comprises" is used followed by "a crosslinking agent." For this reason, it is unclear whether the crosslinking agent is an additional element of the claim or the entire device. In addition, claim 43 now lacks a period. The Examiner suggests changing "comprising" to ---further comprising--- and to add a period in order to overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 8-10, 13-15, and 34-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-11, 14, 15, and 21-29 of copending Application No. 09/014,087. The present claims are obvious over the copending claims because the same embodiment is set forth herein such that the claims set read on each other and are clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641) where the substrate as claimed is the polyalkylimine-coated tissue of Cahalan and the growth factors are coated via glutaraldehyde (a crosslinking agent) to it; see especially column 4, lines 20-43 and column 6, lines 8-28 and the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of normal cell layer"; see column 1, lines 33-43. For this reason, it stimulates the "association of viable cells with the substrate" as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan discloses medical devices/implants where the crosslinking agent glutaraldehyde attaches the growth factor biomolecule and to the substrate-spacer. Cahalan's solid surface can be made of human or animal tissues, but Cahalan lacks the types of tissues claimed.

However, Goldstein teaches that it was known to make similar medical devices/implants out of heart valves, pericardial tissue and the like; see the whole document, especially column 3, lines 14-24.

Therefore, it is the Examiner's position that it would have been obvious to use heart valve or pericardial tissue for Cahalan's solid surface in order to reduce the risk of disease transmission and cost over using human animal tissue. Furthermore, it would have been obvious to use these tissues for the same reasons that Goldstein desires the same.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan fails to disclose the VEGF claimed even though it discloses many other growth factors therewith. Bayne teaches that it was known to use VEGF as the growth factor in a similar fashion within the same art; see the whole document.

Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan so that the implant could be successfully implanted in vascular regions of the body.

Claim 41 and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Sharp et al (WO98/00695), or alternatively, under 35 USC 103(a) by Sharp et al (WO 98/00695) alone. Regarding claim 41, the body of the claim does not require the preamble for completeness such that Tat protein bound to a test substrate reads on the claim language. This Tat protein-to-substrate binding would inherently be done with an

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enzyme-substrate association because enzymes are proteins as are Tat proteins and would have inherently have to be bound in the same way to a substrate.

Alternatively, one could take the position that the binding of the Tat protein to the substrate is not an enzyme-substrate association because it is not explicitly stated as such. However, the Examiner posits that it would have been a matter of obvious design choice to bind the Tat protein to the substrate with an enzyme-substrate association because Applicants have not disclosed that it would provide some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well. Therefore, it would have been an obvious matter of design choice to modify Sharp to obtain the invention as specified in the claims.

With regard to claim 44, the enzyme-substrate association is the type of association which is present in the Sharp device.

Allowable Subject Matter

Claims 28, 29, and 33 are allowed over the prior art of record.

Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are not considered persuasive.

With regard to the traversal of the double patenting rejection, the Examiner notes that no reasons were given for the distinctness of the two claims sets; only the Applicants opinion was given. For this reason, no further comment is deemed necessary.

In response to the argument traversing the Cahalan rejection that Cahalan lacks direct crosslinking of the growth factor to the substrate without a spacer molecule, the Examiner asserts that the claims do not preclude a spacer molecule and that the claims are read on by Cahalan. For this reason, this argument is not commensurate with the scope of the claims.

Applicants argue that the crosslinking agent is used to attach polyalkylimine to the surface not the biomolecules. In reviewing Cahalan, the Examiner found the opposite to be true. Rather, the crosslinking agent (an aldehyde) crosslinks the surface and provides aldehyde functionalities to the surface to bind biomolecules; see column 2, line 66 to column 3, line 3.

In response to the traversal of Cahalan that association of the growth factors is not made by antibody-antigen, specific binding protein, or enzyme associations, the Examiner notes that the association is made by the other association claimed; i.e. the crosslinking agent association.

Applicants also suggest that Cahalan does not teach stimulation of the association of viable cells to the substrate as claimed. However, Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of normal cell layer"; see column 1, lines 33-43. For this reason, the claim language is considered to be fully met in this regard.

In response to the traversal of the Sharp rejection that there is no evidence that the Tat protein of Sharp stimulates the attachment of viable cells to the substrate, the Examiner asserts that claim 41 does not require any particular amount of growth factor. In fact, it appears to only require one molecule of growth factor because no effective amount has been claimed. Furthermore, the Tat protein of Sharp inherently stimulates attachment of viable cells to the substrate, because it is the same molecule as Applicants claim. One cannot get a patent on the discovery of a new property in an otherwise old device.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilo", with a long horizontal line extending to the right.

Paul Prebilo
Primary Examiner
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